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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,209	07/01/2003	JOEL Q. XUE	120683	1208
44702	7590	01/27/2006		
OSTRAGER CHONG FLAHERTY & BROITMAN PC 250 PARK AVENUE, SUITE 825 NEW YORK, NY 10177				
EXAMINER				
GREENE, DANA D				
ART UNIT		PAPER NUMBER		
3762				

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/604,209	Applicant(s) XUE ET AL.	
	Examiner Dana D. Greene	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 13-17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sellers (US 5,228,450, hereinafter “Sellers”). Sellers is considered to disclose:

acquiring high-resolution ECG data from a patient (see col. 2, ln. 40-55, Sellers). The disclosed method of obtaining physiological data is considered to anticipate the claimed method of acquiring high-resolution ECG data from a patient because both methods employ a higher amplifier gain and a higher sampling frequency;

processing said acquired data in accordance with two or more different ECG analysis algorithms (see col. 4, ln. 46-56, Sellers). The disclosed method of processing data using well-known algorithms is considered to anticipate the claimed method of processing acquired data because both relate to methods for multiple algorithm fusion of high-resolution ECG data using signals collected during high-resolution processing to detect new features;

deriving a prediction score for a particular clinical end point as a function of the respective results of said two or more ECG analysis algorithms (see col. 1, ln. 10-25, Sellers). The disclosed method of using the specified monitoring technique is

considered to anticipate the claimed method of deriving a prediction score for a particular clinical end point because both work to identify the time when patients are most at risk of ventricular tachycardia or sudden cardiac death.

With reference to claims 2-5 and 14-17, Sellers is considered to disclose:

training a predictive model with clinically confirmed data for both input and output, wherein said predictive model is used for said prediction score derivation (see col. 1, ln. 10-25, col. 2, ln. 30-40, and col. 4, ln. 46-56, Sellers). The disclosed processor is considered to anticipate the claimed processor because both relate to methods for multiple algorithm fusion of high-resolution ECG data using signals collected during high-resolution processing to detect new features. In this connection, the specified monitoring technique used in the unit is considered to anticipate the claimed processor to derive a prediction score for a particular clinical end point because both work to identify the time when patients are most at risk of ventricular tachycardia or sudden cardiac death.

With reference to claim 13, Sellers is considered to disclose:

a multiplicity of electrodes applied to a patient (see col. 1, ln. 28-35, Sellers).

The disclosed electrodes are considered to anticipate the claimed multiplicity of electrodes because all electrodes are attached at specific locations on the patient;

a data acquisition system for acquiring high-resolution ECG data from the patient (see col. 2, ln. 40-66, Sellers). The disclosed monitor unit is considered to anticipate the claimed data acquisition system because both are used to obtain and record ECG information using analysis-processing hardware;

a processor programmed to process said acquired data in accordance with two or more different ECG analysis algorithms and derive a prediction score for a particular clinical end point as a function of the respective results of said two or more ECG analysis algorithms (see col. 1, ln. 10-25, col. 2, ln. 30-40, and col. 4, ln. 46-56, Sellers). The disclosed processor is considered to anticipate the claimed processor because both relate to methods for multiple algorithm fusion of high-resolution ECG data using signals collected during high-resolution processing to detect new features. Further, the specified monitoring technique used in the unit is considered to anticipate the claimed processor to derive a prediction score for a particular clinical end point because both work to identify the time when patients are most at risk of ventricular tachycardia or sudden cardiac death.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 and 18-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sellers in view of Thiagarajan et al. (US 2003/0060724, hereinafter "Thiagarajan"). Sellers is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed T wave alternans and QT dynamicity algorithms. However, Thiagarajan is considered to disclose the claimed T wave alternans and QT dynamicity algorithms (see col. 3, para. 0018-0019,

Thiagarajan). It would have been obvious to one of ordinary skill in the art to combine the teachings of Sellers with the TWA and QT dynamicity algorithms of Thiagarajan for the purpose of improving the available features for diagnosis using noninvasive electrocardiology.

Claims 9, 11-12, 21, and 23-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sellers in view of Verrier et. al. (US 5,921,940, hereinafter "Verrier"). Sellers is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed acquisition system using the X, Y, and Z leads of a Frank lead system. However, Verrier is considered to disclose the claimed Frank lead system (see col. 30, ln. 10-21, Verrier). It would have been obvious to one of ordinary skill in the art to combine the teachings of Sellers with the frank lead system of Verrier for the purpose of acquiring data from patients and for overall noninvasive ECG detection and diagnosis.

Claims 10 and 22, stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sellers in view of Verrier and further in view of Nearing et al. (US 6,169,919, hereinafter "Nearing"). Sellers and Verrier are considered to disclose the claimed invention as discussed above except for the claimed dividing the high-resolution, averaging beats, and variance determination. However, Nearing is considered to disclose:

dividing the high-resolution ECG data into even beat and odd beat groups (see col. 1, ln. 50-60, Nearing). The disclosed ECG data is used to calculate an odd median

complex for the odd beats in the ECG data and an even median complex for the even beats in the ECG data;

averaging beats in said even and odd beat groups separately (see col. 6, ln. 60-65, Nearing). The disclosed configuration and the claimed method and system both use the signal averaging technique as a method for noninvasive ECG detection and diagnosis such that late potentials are determined on signal averaged ECGs;

determining the variance of T wave morphology of all even, odd, and even & odd averaged beats for each of said X, Y, Z leads (see col. 6, ln. 60-65, Nearing). It would have been obvious to one of ordinary skill in the art to combine the teachings of Sellers and Verrier with the techniques and system taught in Nearing of dividing the high-resolution, averaging beats, and variance determination for the purpose of analyzing electrocardiograms and extracting useful features from an increased volume of acquired data for more efficient and accurate diagnosis of any abnormal heart activity.

Claims 25 and 26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Verrier in view of Nearing et al. (US 6,169,919, hereinafter "Nearing"). Verrier is considered to disclose:

acquiring high-resolution ECG data from a patient using the X, Y, and Z leads of a Frank lead system (see col. 30, ln. 10-21, Verrier). Verrier teaches the use of Frank leads to acquire data from patients. Verrier is considered to disclose the claimed invention as discussed above, except for the claimed dividing the high-resolution, averaging beats, and variance determination. However, Nearing is considered to disclose:

dividing the high-resolution ECG data into even beat and odd beat groups (see col. 1, ln. 50-60, Nearing). The disclosed ECG data is used to calculate an odd median complex for the odd beats in the ECG data and an even median complex for the even beats in the ECG data;

averaging beats in said even and odd beat groups separately (see col. 6, ln. 60-65, Nearing). The disclosed configuration and the claimed method and system both use the signal averaging technique as a method for noninvasive ECG detection and diagnosis such that late potentials are determined on signal averaged ECGs;

determining the variance of T wave morphology of all even, odd, and even & odd averaged beats for each of said X, Y, Z leads (see col. 6, ln. 60-65, Nearing). It would have been obvious to one of ordinary skill in the art to combine the teachings of Verrier with the techniques and system taught in Nearing of dividing the high-resolution, averaging beats, and variance determination for the purpose of analyzing electrocardiograms and extracting useful features from an increased volume of acquired data for more efficient and accurate diagnosis of any abnormal heart activity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana D. Greene

Dana D. Greene

George Manuel
George Manuel
Primary Examiner